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Section 5: 510(k) Summary

Submitter's Name and Address	Mylad Orthopedic Solutions, LLC 8803 Windy Creek Way McLean, Virginia 22102 Phone: (793)738-6547 Facsimile: (661)885-4447
Contact Person	Scott Edwards, M.D.
Date of Summary:	
Proprietary Name of Device:	OlecraNail™ Intramedullary Fixation System
Common/Usual Name:	intramedullary nail
Classification Name:	Rod, Fixation, Intramedullary and Accessories per 21 CFR section 888.3020
Legally Marketed Equivalent Devices:	Synthes Intramedullary Nail for the Olecranon (K073402) Acumed Small Bone Locking Rod System (K071944) Plus Orthopedics IP-XS Compression Nail System (K032548) Acumed Polarus Nail (K920666)

Summary of Device:
The OlecraNail™ intramedullary rod is a solid bore, stainless steel, tapered rod that is inserted into a pre-drilled hole into the medullary canal of the proximal ulna. Once the device is in place, a combination stainless steel/polyphenylsulfone guide is used to drill into the bone and insert several screws through the bone and rod to secure all bone fragments and lock the rod into position. During this process, compression at the fracture site may be obtained by manually turning a knob to activate the compression mechanism. After all screws are placed, the guide may then be detached using a break-away mechanism.

Intended Use:
This device is intended for the surgical fixation of all fractures and surgical osteotomies of the proximal ulna in the acute or chronic settings. This intended use is quite similar to the indications of the predicate devices and does not raise issues of safety or effectiveness.

Technological Characteristics of the Device Compared to the Predicate Devices:
The material, design, and intended use of the OlecraNail™ Intramedullary Fixation System are identical or similar to at least one of the listed predicates. The OlecraNail™ implant is made from 316L VM stainless steel in conformance with ASTM-F138 with multiple transverse holes for interlocking components, which is the identical material of all three predicates. The OlecraNail™ implant is tapered from 7 mm proximally to 5 mm distally similarly to its predicate, Acumed Polarus Nail (K920666). Its length is 100 mm, which is similar to Plus Orthopedics/Smith and Nephew IP-XS Compression Nail System (K032548) which is 99 mm. The external threads of the locking screws engage the internal threads of the nail similar to Acumed Polarus Nail (K920666). Compression may be obtained by axially moving the nail within the bone, in a similar mechanism as demonstrated by Plus Orthopedics IP-XS Compression Nail System (K032548). Detachment of the nail from the guide is achieved by a break-away mechanism commonly used in orthopedics, such as Knowles Pins (K983757). There are no technological characteristics that raise new issues of safety or effectiveness.

Non-Clinical Tests:
Three tests were performed on OlecraNail™ intramedullary rods. The first test, the three-point bending test, was similar in protocol to the four-point bending test described in ASTM-F1264. In this bending test, the OlecraNail™ intramedullary rod demonstrated equal or superior elastic limits and rigidity compared to commonly used implants for identical indications. In the second test, the OlecraNail™ intramedullary rod demonstrated a higher torsional strength than would be sustainable by the screws that would be used to stabilize the nail in the bone. The final test, which subjected the rod-guide junction to bending and torsional stresses, showed that the assembly can tolerate significant stresses beyond what would be seen in a standard operative setting. These three tests indicate that the OlecraNail™ intramedullary rod and assembly will support the *in vivo* loads expected to be seen for this application.

Miscellaneous Information:

All screws used in this System are covered by a pre-existing premarket notification clearance, K002486.

The stainless steel (316L VM) for all parts is supplied, inspected, and certified by Orchid Design to meet ASTM-F138.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mylad Orthopedic Solutions, LLC
% Scott G. Edwards, M.D.
President
8803 Windy Creek Way
McLean, Virginia 22102

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Re: K081356
Trade/Device Name: OlecraNail ™ Intramedullary Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulation Class: Class II
Product Code: HSB
Dated: June 24, 2008
Received: June 26, 2008

Dear Dr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Statement of Indications for Use

510(k) Number K081356

Device Name: OlecraNail™ Intramedullary Fixation System

Indications for Use:

The OlecraNail™ Intramedullary Fixation System and accessories are intended for the surgical fixation of all fractures and surgical osteotomies of the proximal ulna in the acute or chronic setting.

Prescription Use X OR Over The Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081356